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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|------------------|
| 10/501,881 | 07/20/2004 | Jeffrey Kane | 440894/PALL | 9012 |
| 23548 7590 04/20/2007 LEYDIG VOIT & MAYER, LTD 700 THIRTEENTH ST. NW SUITE 300 WASHINGTON, DC 20005-3960 | | | EXAMINER EPPERSON, JON D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1639 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/501,881 | Applicant(s) KANE, JEFFREY | |
| | Examiner Jon D. Epperson | Art Unit 1639 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

SUBSTITUTE RESTRICTION

1. The Response to the Restriction Requirement filed on February 6, 2007 is acknowledged.
2. Upon further review of the case all previous restriction and election of species requirements are hereby withdrawn and a new substitute restriction and/or election of species is now required (see below). Please also note the change in Examiner from Doug Schultz to Jon Epperson.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
4. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.
 - I. Claims 1-13 and 18-21 drawn to a product described as an analysis device.
 - II. Claims 14-16 drawn to a method for making an analysis device
 - III. Claim 17 drawn to a method for analyzing biomolecules using an analysis device.

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5. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons that follow.

6. PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.” It further defines “special technical feature” as “those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art.”

7. The technical feature here is the “analysis device” comprising a microporous membrane integrally bonded to a non-porous injection molded polymeric support. The groups lack unity because this technical feature is known in the art as disclosed by Jao et al. (Jao et al. “Interphase bond strength and energy absorption of injection-molded rubber-coated glass/nylon composites” Journal of Reinforced Plastics and Composites **1992**, *11*, 811-825). This reference is described below.

8. Jao et al. disclose injection molded glass/nylon composites including rubber coated composites that possess a “nylon” microporous polymeric membrane that is “integrally bonded” to either the glass or the rubber. Thus, Applicants’ claimed analysis device was known in the art.

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9. Therefore, the technical feature linking the inventions of groups I-III does not constitute a species technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

10. Accordingly, groups I-III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Species Election

11. This application contains claims directed to more than one species of the generic invention for Groups I-III. These species are deemed to lack unity of invention because they are not so linked to form a single general inventive concept under PCT Rule 13.1. Claims 1, 14, and 17 are generic for Groups I, II, and III, respectively.

12. If applicant elects any one of the invention of Groups I-III applicant is required to elect from the following patentably distinct species.

Subgroup 1: Species of polymer membrane (e.g., see claim 1)

Applicant must elect for purposes of search a *single species* of polymer membrane. Please elect, in addition to a "class" of polymer membranes (e.g., sulfone), a specific polymer membrane within that class bisphenol A polysulfone (e.g., see specification, page 9, paragraph 47) wherein all atoms and bonds are defined by said election.

Subgroup 2: Species of support (e.g., see claims 1, 12)

Applicant must elect for purposes of search a *single species* of support (e.g., polyolefin).

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13. If applicant elects the invention of Groups III applicant must additionally elect the following species.

Subgroup 3: Species of biomolecule (e.g., see claim 17)

Applicant must elect for purposes of search a *single species* of biomolecule (e.g., DNA).

14. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons.

15. PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". It further defines "special technical feature" as "those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art". For example, unity of invention is fulfilled if:

- (a) all alternatives have a common property; **and**
- (b) (i) a common structure is present, i. e. a significant structural element is shared by all alternatives, or
- (b) (ii) in cases where the common structure can not be the unifying criterion, all alternatives belong to a recognized class of compounds in the art to which the invention pertains. (MPEP 1850).

16. According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure, which is a "significant" structural element. Here, the materials defining the polymer "membranes" encompass a wide range of materials that do not share a common core structure (e.g., polyolefins, polyamides, etc.). For example, polyolefins possess an "olefin" core structure

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whereas polyamides possesses an “amide” core structure. Furthermore, these materials do not all belong to an art-recognized class of compounds (e.g., polysulfone is classified variously, for example, in class 525, subclass 906; polyamide; such as nylon, can be classified in class 525, subclass 926). Likewise, the species of “support” do not share a common core structure. For example, polyolefin contains an “olefin” core structure whereas polycarbonate contains a “carbonate” core structure. In addition, these materials do not belong to an art-recognized class of compounds (e.g., polyolefin is classified variously, for example, in class 585, subclass 326; polycarbonate can be classified in class 524, subclass 537). Finally, the species of biomolecule also do not share a common core structure. For example, DNA is made up of nucleotides whereas proteins are made from amino acids (i.e., completely different building blocks). In addition, these polymers do not belong to an art-recognized class of molecules (e.g., peptides/proteins in 530, subclass 300+; nucleic acid class 536, subclass 23.1). The species also do not possess a common property (e.g., nucleic acid “hybridize” to target molecules, proteins do not; nucleic acids store genetic information, proteins do not, etc.). In addition, According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. Thus, even if assuming *arguendo* that all of the claimed alternatives did have a “significant” common structure (which is not the case, see above) the compounds would not be regarded as being of similar nature because the shared common structure is not a contribution over the prior art. That is, the “special technical feature” of Groups I-III lack novelty or inventive step over (see above).

For these reasons, election under these rules is proper and required.

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17. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

18. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

19. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

20. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

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21. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

22. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

23. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

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103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoiner in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoiner.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.

April 11, 2007

JON EPPERSON
PRIMARY EXAMINER



